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UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:)
Fisher et al.) Attorney Docket No. 1781-0003
Application No. 10/070,524) Examiner: To be assigned
Filed: March 6, 2002)
Title: Orthopaedic Joint Prosthesis) Group Art Unit: To be assigned

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on July 10, 2002
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July 10, 2002

Date of Signature

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 CFR §1.56, Applicants hereby disclose the following references, copies of which are enclosed, regarding the above-identified patent application.

<u>U.S. Patent Number</u>	<u>Inventor</u>	<u>Issue Date</u>
4,145,764	Suzuki et al.	
4,687,487	Hintermann	09/18/1987
5,037,438	Davidson	08/06/1991
5,641,323	Caldarise	06/24/1997
5,788,916	Caldarise	

<u>Foreign Patent Number</u>	<u>Country</u>	<u>Issue Date</u>
EP 0 821922 A	European	02/04/1998
EP 0 841 041 A	European	05/13/1998
WO 97/16137	PCT	05/09/1997
WO 97/31592	PCT	09/04/1997

<u>Other Articles</u>	<u>Authors</u>	<u>Country</u>	<u>Date</u>
XP 000583024	Willmann G. et al.	Germany	04/01/1996
XP 000541644	Bosdorf K. et al.	Germany	12/01/1995
XP 002154221	Hennig F. F. et al.	Germany	09/1992
XP 002154222	Ungethüm M. et al.	Germany	11/1982

A copy of an International Search Report for the corresponding International Application No. PCT/GB 00/03428 is also enclosed. Also enclosed is a copy of a Search Report for UK patent application GB 9921145.0 to which priority is being claimed.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language documents cited above and on the accompanying form PTO-1449:

German article XP 000583024 contains the following disclosure: At the articulating components of a total hip prosthesis are the spherical femoral head and the acetabular cup. Particularly high rates of wear are seen with cups made of polyethylene, and the abrasion particles cause osteolysis, which often makes surgical revision necessary. Despite considerable progress in the development of total hip replacement systems over the last 20 years, there is a need to eliminate or further minimize the problem of osteolysis, which is also referred to as polyethylene disease. Clinical experience over the last 20 years has shown that by using BioloX (medical grade alumina) femoral head and acetabular cups it is possible to achieve very low wear rates, which histological studies have shown to be readily tolerated. The secondary conditions needed to develop modern modular ceramic acetabular cup inserts are discussed. For the fixation of cup inserts, the well known taper fixation concept has proved to be of value. A concept taking into account the needs of the surgeon and the manufacturing constraints applying to ceramic materials is proposed.

German article XP 000541664 contains the following disclosure: A review of current clinically applied biomaterials for the femoral heads and acetabular cups of total hip prostheses (UHMWPE, CoCrMo alloys, alumina and zirkonium) in terms of their resistance to wear is

presented. Further developments in metallic and ceramic materials over the last few years have now left UHMWPE as the weakest link in the prosthesis material chain. Alternative materials aimed at improving the tribological properties of the femoral head/acetabular head system are presented. New surface hardening and coating techniques for titanium alloys, polymer coatings, optimized UHMWPE, as well as various carbon-fiber-reinforced synthetic materials are described. The advantages, disadvantages and prospects of these materials are compared with those of standard materials and documented in experimental and clinical studies.

German article XP 002154221 contains the following disclosure: Today, only hard/soft cup and femoral head combinations are employed for hip joint prostheses. Highly polished ceramic is a material with very good tribological properties for femoral heads, being highly resistant to mechanical wear and tear, and highly resistant to chemical reactions in the biological environment. The advantage of metal heads, in contrast, undoubtedly lies in their resistance to breakage the ease with which their geometry can be modified with respect, for example, to antirotation angle and neck length. The ideal material for femoral heads is a combination of the two materials. The new multi-layer combination of titanium-niobium oxide/nitride ceramic coating applied to a prehardened titanium head combines the positive material properties in an ideal manner. Femoral heads made of CoCrMo, oxide-hardened titanium, aluminum oxide or multi-layer titanium-niobium ceramic were compared by means of friction and wear and tear tests. The TiNb-ceramic-metal heads showed similar abrasion at the surface as the ceramic heads. At the high loads of more than 400kp, which may also be reached under physiological conditions, the specially coated titanium-ceramic heads proved to be superior in terms of resistance to fracture and tribological properties.

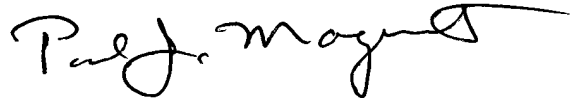
German article XP 002154222 contains the following disclosure: In vivo as well as in simulator tests the different types of knee endoprotheses show a varying tribological behavior. In order to point out some of the many influences for these characteristics, we developed a model testing machine which, because of its simple construction, enables us to vary the most important parameters individually and therefore their influences on the wear rate and wear mechanisms can be studied. By this method it is possible to show that the geometry

of the articulating surfaces in the sagittal plane as well as their roughness are very important for the tribological behavior of the prosthesis. The wear mechanisms, which are dependent on these parameters, can be seen on SEM-pictures of the worn gliding surfaces. _

It is believed that no fees are due for the consideration of this Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 13-0014, but not to include any payment of issue fees.

Respectfully submitted,

MAGINOT, MOORE & BOWMAN

A handwritten signature in black ink, appearing to read "Paul J. Maginot", with a long horizontal flourish extending to the right.

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